ForPatients
by Roche

Advanced Solid TumorsMetastatic Solid Tumors

A Study to Evaluate the Safety, Pharmacokinetics, and Activity of GDC-1971 in Combination With Atezolizumab in Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	6 Countries	NCT05487235 2021-006479-40 GO43712

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase Ib, Open-Label Study Evaluating the Safety, Pharmacokinetics, and Activity of GDC-1971 in Combination With Atezolizumab in Patients With Locally Advanced or Metastatic Solid Tumors

Trial Summary:

The purpose of this study is to evaluate the safety, pharmacokinetics (PK), and activity of GDC-1971 when administered in combination with atezolizumab in participants with locally advanced or metastatic solid tumors. The study will have 2 stages- dose finding stage and expansion stage. In expansion stage participants with non-small cell lung cancer programmed death ligand -1 high (NSCLC PD L-1 high), NSCLC PD L-1 low, head and neck squamous cell carcinoma (HNSCC) PD L-1 positive, BRAF wild type (BRAF WT) melanoma and any locally advanced or metastatic solid tumors will be enrolled.

Genentech, Inc.	Phase 1
Sponsor	Phase

NCT05487235 2021-006479-40 GO43712
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

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- Has Eastern Cooperative Oncology Group(ECOG) Performance Status of 0 or 1
- Has Life expectancy >= 12 weeks
- Adequate organ function
- Measurable disease per Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1).

Inclusion Criteria for Dose-Finding Stage:

- Histologically confirmed locally advanced or metastatic solid tumor that has progressed after at least one available standard therapy or for which approved standard therapy has proven to be ineffective or intolerable

Inclusion Criteria for Expansion Stage: NSCLC Cohort

- Histologically confirmed locally advanced or metastatic NSCLC
- Absence of epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK)
- PD- L1 positive
- No prior systemic therapy for locally advanced or metastatic NSCLC

Inclusion Criteria for Expansion Stage: HNSCC Cohort

- Histologically confirmed recurrent, or metastatic HNSCC
- PD-L1 positive
- No prior systemic therapy for recurrent or metastatic HNSCC

Inclusion Criteria for Expansion Stage: BRAF WT melanoma Cohort

- Histologically confirmed locally advanced or metastatic or unresectable locally advanced cutaneous BRAF WT melanoma or melanomas of unknown primary that are non-mucosal and non -uveal that has progressed on or after treatment that included anti PD1 or anti PD-L1 therapy

Inclusion Criteria for Expansion Stage: Other Advanced or Metastatic Solid Tumors Cohort

- Histologically confirmed locally advanced or metastatic solid tumor that has progressed after at least one available standard therapy or for which approved standard therapy has proven to be ineffective or intolerable, standard therapy is considered inappropriate, or an investigational agent is a recognized standard of care

Exclusion Criteria:

- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases.
- Has leptomeningeal disease or carcinomatous meningitis
- Has uncontrolled hypertension
- Has left ventricular ejection fraction < institutional lower limit of normal or < 50%
- Has clinically significant history of liver disease including viral or other hepatitis, current alcohol abuse, or cirrhosis
- Has an active or history of autoimmune disease or immune deficiency including myasthenia gravis, myositis, autoimmune hepatitis, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, vascular thrombosis associated with antiphospholipid syndrome, Wegener's granulomatosis, Sjögren's syndrome, Guillain-Barré syndrome, multiple sclerosis, vasculitis, or multiple sclerosis. Participants with a history of autoimmune- related hypothyroidism on thyroid replacement hormone or with controlled Type I diabetes mellitus on a stable dose of an insulin regimen are eligible for this study

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